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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/465,718	12/17/1999	JEAN-LOUIS DASSEUX	9196-018-999	9219

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/28/2001

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/465,718

Applicant(s)
Dasseux et al

Examiner
Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 12, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above, claim(s) 14-35 and 43-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 36-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Status of Claims

1. Applicant's election without traverse of Group I, claims 1-18, 36-40, in communication filed 9/12/01 (paper No.7) is acknowledged. It is noted that claims 41,42 have been inadvertently omitted from claims of Group I: these claims are a part of Group I. Claims 19-35, 43-55 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups.

Further restriction

2. Upon further consideration of the restriction requirement made in the previous Office action the following additional restriction of Group I was deemed necessary.

I.1 Claims 1-9, 12-19, 36-42, drawn to ApoA-I agonist comprising peptides of formula I, classified in class 530, subclasses 300, 324-326, and class 514, subclass 12-13.

I.2 Claims 1-13, 36-42, to the extent drawn to deletion analogues of ApoA-I agonist peptides of formula I, classified in class 530, subclass 324-327; and class 514, subclasses 12-14.

The deletion analogues of the peptides of formula I, are independent and/or distinct from the full-length peptides of formula I because they are structurally

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different compounds which do not have a common core structure, have different amino acid content and length and thus are expected to have different physico-chemical properties and separate manufacture and/or use. Additionally, the deletion analogues require different and burdensome bibliographical, sequence and structure searches as compared to search require for peptides of group I.

During the above telephone conversation, applicant's representative. Raul Pathak, agreed to elect the Group I.2, drawn to deletion analogs. Applicant is encouraged to amend the claims to conform to this election by canceling the nonelected subject matter (claims 2-9, 12-19) and amending claims 1 and 36-42 to read on the elected group.

Accordingly, claims 14-18 are withdrawn from consideration as drawn to non-elected subject matter.

Claims 1-13, 36-42 are under consideration only to the extent that they read on the elected Group I invention.

In regard to election of species, applicant elected peptides comprising SEQ ID No. 146. Insofar as the elected compounds have been found to be neither anticipated nor rendered obvious by the prior art, the Examiner has extended his search to include all deletion analogs derived from peptides of formula 1.

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Claim Objections

3. Claims 1-13, 36-42 are objected to because of the following informalities:

In claim 1-13, 36-42 it is not clear, whether the term "ApoA-I agonist" refers to compound or composition. Amending to recite "ApoA-I agonist compound" will overcome this objection.

Claim Rejections - 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9, 12-17, 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, it is not clear, how the term "peptide analogue" for "Z2" substituent (p. 134, line 6) modifies the term "peptide analogue" which occurs in the beginning of the claim (e.g., line 2).

B. In claim 1, "X_n" (p. 134, line 7) lacks clear antecedent basis. Amending the claim to recite the actual X substituents and Z2 substituent, e.g., "between

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residues X_1 to X_{23} and between residues of the peptide Z " will overcome this rejection.

C. In claim 4, line 1, there is no clear antecedent basis for the term "the hydrophobic residues". Amending to rewrite as "hydrophobic residues" will overcome the rejection.

D. In claim 6, line 1, there is no clear antecedent basis for the term "the hydrophilic residues". Amending to rewrite as "hydrophilic residues" will overcome the rejection.

E. In claim 9, the phrases "the substituting residue" and "the substituted residue" lack clear antecedent basis. Amending to rewrite as "the conservatively substituting residue" and "the conservatively substituted residue" will overcome the rejection.

Claim Rejections - 35 U.S.C. § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 1-13, 36-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for full-length peptides of formula 1, does not reasonably provide enablement for any deletion analog of said peptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to deletion analogs wherein up to eight residues selected from any one from X1 to X22 are deleted. The residues can be deleted at any random order. The only disclosed utility for the claimed peptides is being ApoA-1 agonists. The specification clearly describes on pages 25-46 that the peptides must conform to various structural requirements in order to display the expected utility. Deletion of a substantial, up to eight residues, portion of the peptide structure will inevitably alter both the structural and functional properties of peptide analogs. The amino acid sequence of the peptide is of great importance in determining the secondary and tertiary structures of the peptide. This is because the peptide's structure is determined by the interplay of the hydrophobic/hydrophilic, steric and electrostatic forces among the linked amino acid residues. Deleting a single residue alters these forces unpredictably and, consequently, may alter bioactivity unpredictably. The specification does not disclose a core structure required for the deletion analogs to maintain their biological activity. The guidance present in specification is, in fact,

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proving the unpredictability of the claimed subject matter: p.51, first paragraph describes that, in order to retain activity, a full α -helix turn consisting of 3-4 residues must be deleted. This, clearly, will not be achieved by deletion of, e.g., 6 residues, which is within the claimed scope of deletion analogs. Further, specification emphasizes importance of the basic moiety at C-terminus (p. 51, second paragraph); however the scope of the claims encompass any analogs with deletions at random order.

In view of the above, it is the Examiners position that with the insufficient guidance and working examples in regard to deletion analogues, one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

6. Claims 1-13, 36-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptide analogues of claim 1, wherein each bond between residues X1-X23 and the bonds between residues of peptide Z2 are an amide linkage, a substituted amide linkage, an isostere or an amide mimetic (as described in specification, pages 28-29), does not reasonably provide enablement for peptides having a "peptide analogue" in Z2 radical (see claim 1, p. 134, line 6). The specification does not enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification, pages 28-29, describe specific types of substituted amides, amide isosteres or amide mimetics for the core peptides of Figure 1 which would allow one of ordinary skill to make and use the resulting peptides without undue experimentation. However, the 1-7 residue peptide Z2 as claimed in claim 1, is also drawn to "peptide analogues" (see claim 1, p. 134, line 6) which are not necessarily limited to peptides and peptide mimetics described in specification. "Peptide analogue" is an unduly broad term which may refer to either to analogous structure (e.g., peptide sequence) and/or function (e.g., therapeutic properties), and/or conformation (e.g., three dimensional parameters for binding bio-active molecules), the parameters of which are neither described, nor representative examples are provided as to enable the skilled artisan to practice the presently claimed invention without undue experimentation. For example, the requisite computer algorithms and/or techniques are not adequately described in the specification as to permit the skilled in the art to "model" the claimed peptide so as to determine any requisite secondary and/or tertiary conformation necessary to arrive at a peptide analogue. It is not possible to predict the effect of replacing a single amino acid residue in a peptide's structure or bioactivity. The amino acid sequence of the peptide is of great importance in determining the secondary and tertiary structures of the peptide. This

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is because the peptide's structure is determined by the interplay of the hydrophobic/hydrophilic, steric and electrostatic forces among the linked amino acid residues. Therefore, changing a single residue alters these forces unpredictably, and impose a new unpredictable structure of the modified peptide. Therefore, if replacing one or more residues in a peptide unpredictably alters its structure, this replacement also may alter bioactivity unpredictably. The specification does not describe analogues in terms of degree of homology and/or means of measuring homology which are necessary to practice the presently claimed invention. Nor does the specification discuss what properties and the degree of those properties (therapeutic or otherwise) are necessary to make and/or use a peptide analogue within the scope of the claimed invention.

In view of the above, it is the Examiners position that with the insufficient guidance and working examples in regard to "peptide analogues" of Z2, and in view of unpredictability and the state of art, one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by

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a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-13, 36-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over U.S. Patent Nos. 6004925, 6037323, and 6265377. Although the conflicting claims are not identical, they are not patentably distinct from each other because, first the instant claims are drawn to peptides comprising deletion analogs; consequently, the issued patents claiming full length peptides read on peptides comprising deletion analogs as instantly claimed. Second, 6037323 and 6265377 are drawn to "deletion analogs" as they claim peptides in which X19-X22 residues, present in the instantly claimed full length peptides, are absent. Further, up to eight residues in peptides of 6265377 patent can be deleted. See claims 1, 27.

Conclusion.

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8. Claims 1-13, 36-42 are novel and unobvious over the prior art of record or any combination thereof because the deletion analogs of peptides of claim 1 are not disclosed or suggested by the prior art of record.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November 27, 2001

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

